

Attorney Docket No.: PTQ-0065
Inventors: Jonathan M. Lee
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REMARKS

Claims 1-30 are pending in the instant application.

Claims 1-30 have been subjected to the following

Restriction Requirement:

Group I, claims 1-6, as specifically drawn to a method for diagnosing cancer comprising measuring EEF1A2 gene amplification;

Group II, claims 1-6, as specifically drawn to a method for diagnosing cancer comprising measuring EEF1A2 mRNA levels;

Group III, claims 1-6, as specifically drawn to a method for diagnosing cancer comprising measuring EEF1A2 protein levels;

Group IV, claims 1-6, as specifically drawn to a method for diagnosing cancer comprising measuring EEF1A2 protein activity;

Group V, claim 7, as specifically drawn to a kit for prognosticating and/or diagnosing cancer comprising means for measuring EEF1A2 gene amplification;

Group VI, claim 7, as specifically drawn to a kit for prognosticating and/or diagnosing cancer comprising a means for measuring EEF1A2 mRNA levels;

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Group VII, claim 7, as specifically drawn to a kit for prognosticating and/or diagnosing cancer comprising a means for measuring EEFlA2 protein levels;

Group VIII, claim 7, as specifically drawn to a kit for prognosticating and/or diagnosing cancer comprising a means for measuring EEFlA2 protein activity;

Group IX, claims 8-28, as specifically drawn to a method of inhibiting EEFlA2 expression in a tumor cell and a method of treating cancer comprising administering to a patient an inhibitor of EEFlA2 expression;

Group X, claims 24 and 26-28, as specifically drawn to a method of treating cancer comprising administering to a patient an inhibitor of EEFlA2 activity;

Group XI, claims 29-30, as specifically drawn to a screening assay comprising measuring an agent's ability to inhibit EEFlA2 expression; and

Group XII, claims 29-30, as specifically drawn to a screening assay comprising measuring an agent's ability to inhibit EEFlA2 activity.

The Examiner suggests that Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or

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corresponding technical features. In particular, the Examiner suggests that the technical feature linking Groups I-XII is the EEF1A2 gene. However, the Examiner suggests that the EEF1A2 gene was taught by Lund et al. (Genomics 1996 36:359-361).

Applicant respectfully traverses this Restriction Requirement.

At the outset, Applicant would like to clarify for the record that Groups I-IV, claims 1 through 6, have claims drawn to a method for prognosticating survival and selecting an effective treatment regime for a patient suffering from cancer as well as claims drawn to a method for diagnosing cancer.

Further, it is respectfully pointed out that the Examiner's suggestion that "the inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature" directly contradicts both the Search Report and the Written Opinion issued in the PCT application of which this case is the U.S. National Stage.

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Applicant also respectfully disagrees with the Examiner's suggestion that the EEFlA2 gene is the technical feature linking Groups I-XII. The technical feature linking Groups I-XII is not simply the EEFlA2 gene, but rather the inventor's recognition for the first time that expression of the EEFlA2 gene is associated with and can confer oncogenic properties on a cell including enhancing focus formation, allowing anchorage independent growth and decreasing the doubling time of fibroblasts, promoting *in vivo* tumorigenicity in fibroblasts and increasing the growth rate and *in vivo* tumorigenicity of carcinoma cells. This technical feature is neither taught nor suggested by Lund et al. Thus, Applicants believe the basis for this Restriction Requirement is flawed.

In addition, MPEP §803 provides two criteria which must be met for a restriction requirement to be proper. The first is that the inventions be independent or distinct. The second is that there would be a serious burden on the Examiner if the restriction is not required. A search of the prior art relating to pending claims 1-30 has already been performed in the PCT application. Thus, there should be no burden placed upon the Examiner by

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including all claims in this case, since the full claim set was already searched and examined in the PCT application.

Further, the Examiner has provided no evidence whatsoever in this Restriction Requirements to support the contention that the Groups have acquired separate status in the art.

Accordingly, reconsideration and withdrawal of this Restriction Requirement is respectfully requested.

However, in an earnest effort to be completely responsive, Applicants elect to prosecute Group III, claims 1-6 with traverse.

Claims of Group III have further been subjected to a species election requirement. The Examiner suggests that claims 1, 2, 4 and 5 of this Group are generic to a plurality of disclosed patentably distinct species of cancers and tumor cells corresponding to said cancers comprising ovarian cancer and ovarian cancer cells, breast cancer and breast cancer cells and colorectal cancer and colorectal cancer cells.

Applicants respectfully traverse this species election requirement.

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In accordance with MPEP § 808.01, an election of species should be made when a generic claim recites such a multiplicity of species that an unduly extensive and burdensome search is required. In the instant case, however, the generic claim is not drawn to such a large multiplicity that search of all species would be unduly extensive or burdensome. Only 3 cancer types have been set forth by the Examiner as different species. Further, a proper search of the generic claims drawn to methods for diagnosing cancer and prognosticating survival and effect of treatment regimes in cancer patients, should reveal any art relating to various cancer types which the Examiner suggests to be distinct species. Accordingly, reconsideration of this species election requirement is respectfully requested.

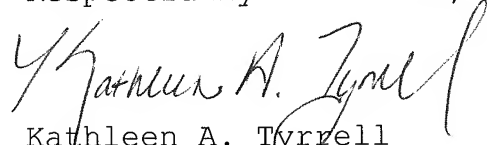
In an earnest effort to be completely responsive, however, Applicants elect breast cancer and breast cancer cells, with traverse.

In accordance with MPEP § 809.01 and 37 C.F.R. § 1.146, it is respectfully pointed out that the claims should only be restricted to this species if no generic claim is held allowable.

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Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

Respectfully submitted,


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